

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)
 PAR STERILE PRODUCTS, LLC, and)
 ENDO PAR INNOVATION)
 COMPANY, LLC,)
) C.A. No. 18-823-CFC
 Plaintiffs,)
)
 v.) **PUBLIC VERSION**
)
 EAGLE PHARMACEUTICALS INC.,)
)
 Defendant.)

DECLARATION OF ASHLEY CADE

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Dated: April 17, 2020
6665415 / 45185

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COMPANY, LLC,)	
)	C.A. No. 18-823-CFC
Plaintiffs,)	
)	
v.)	PUBLIC VERSION
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

DECLARATION OF ASHLEY CADE

I, Ashley Cade, declare pursuant to 28 U.S.C. § 1746 as follows:

1. I am an attorney at the law firm Kirkland & Ellis LLP, representing Eagle Pharmaceuticals, Inc. (“Eagle”) in the above-captioned litigation.

2. I submit this declaration upon my personal knowledge in support of Eagle’s Concise Statement of Facts In Support of Its Motion For Summary Judgment of Non-Infringement.

3. Attached hereto as Exhibit 1 is a true and correct copy of excerpts of the Approval Letter for NDA No. 204485, dated April 17, 2014.

4. Attached hereto as Exhibit 2 is a true and correct copy of excerpts of the Approval Letter for NDA No. 204485/S-003, marked received March 21, 2016.

5. Attached hereto as Exhibit 3 is a true and correct copy of an email from Brian Goldberg to Ashley Cade, dated March 17, 2020.

6. Attached hereto as Exhibit 4 is a true and correct copy of excerpts of U.S. Patent No. 9,687,526.

7. Attached hereto as Exhibit 5 is a true and correct copy of excerpts of U.S. Patent No. 9,744,209.

8. Attached hereto as Exhibit 6 is a true and correct copy of excerpts of U.S. Patent No. 9,750,785.

9. Attached hereto as Exhibit 7 is a true and correct copy of an email from Sharon Gagliardi to Christopher Citro, dated September 6, 2019.

10. Attached hereto as Exhibit 8 is a true and correct copy of excerpts of Plaintiffs' Second Supplemental Objections and Responses to Eagle Pharmaceuticals Inc.'s First Set of Interrogatories (Nos. 4-10, 12-13), dated August 26, 2019.

11. Attached hereto as Exhibit 9 is a true and correct copy of excerpts of the Paragraph IV Acknowledgement ANDA Receipt Letter for ANDA No. 211538, dated April 12, 2018.

12. Attached hereto as Exhibit 10 is a true and correct copy of Module 1.12.12 Comparison of Generic Drug and RLD, [REDACTED] of ANDA No. 211538 [REDACTED]

13. Attached hereto as Exhibit 11 is a true and correct copy of the Highlights of Prescribing Information for VASOPRESSIN INJECTION, [REDACTED] of ANDA No. 211538 [REDACTED].

14. Attached hereto as Exhibit 12 is a true and correct copy of excerpts of Module 2 Supplement: Question-based Review for Drug Product, [REDACTED] of ANDA No. 211538 [REDACTED].

15. Attached hereto as Exhibit 13 is a true and correct copy of excerpts of the Approval Letter for NDA No. 204485/S-002, dated May 7, 2015.

16. Attached hereto as Exhibit 14 is a true and correct copy of excerpts of Module 3.2.P.5.1 Specifications, [REDACTED] of ANDA No. 211538 [REDACTED].

17. Attached hereto as Exhibit 15 is a true and correct copy of Module 3.2.P.5.1 Specifications, [REDACTED] of ANDA No. 211538 [REDACTED].

18. Attached hereto as Exhibit 16 is a true and correct copy of excerpts of Module 3.2.P.8.1 Stability Summary and Conclusion, [REDACTED] of ANDA No. 211538 [REDACTED].

19. Attached hereto as Exhibit 17 is a true and correct copy of excerpts of Module 3.2.P.3.3 Description of Manufacturing Process and Process Controls, [REDACTED] of ANDA No. 211538 [REDACTED].

20. Attached hereto as Exhibit 18 is a true and correct copy of excerpts of the Executed Batch Record [REDACTED] of ANDA No. 211538 [REDACTED].

21. Attached hereto as Exhibit 19 are true and correct copies of excerpts of:

- a. Stability Data for [REDACTED];
- b. Stability Data for [REDACTED];
- c. Stability Data for [REDACTED];
- d. Stability Data for [REDACTED];
- e. Stability Data for [REDACTED];
- f. Stability Data for [REDACTED];
- g. Stability Data for [REDACTED];
- h. Stability Data for [REDACTED]; and
- i. Stability Data for [REDACTED],

[REDACTED] of ANDA No. 211538 [REDACTED].

22. Attached hereto as Exhibit 20 is a true and correct copy of [REDACTED] [REDACTED] dated March 28, 2019.

23. Attached hereto as Exhibit 21 is a true and correct copy of excerpts of the Opening Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement of U.S. Patent Nos. 9,687,526, 9,744,209, and 9,750,785, dated November 15, 2019.

24. Attached hereto as Exhibit 22 is a true and correct copy of excerpts of the Reply Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement, dated January 20, 2020.

25. Attached hereto as Exhibit 23 are true and correct copies of excerpts of:

- a. Stability Data for Batch [REDACTED] dated January 20, 2020;
- b. Stability Data for Batch [REDACTED] dated January 20, 2020;
- c. Stability Data for Batch [REDACTED] dated January 22, 2020;
- d. Stability Data for Batch [REDACTED], dated January 22, 2020;
- e. Stability Data for Batch [REDACTED], dated January 22, 2020;
- f. Stability Data for Batch [REDACTED], dated January 22, 2020; and
- g. General Notebook for [REDACTED], dated April 1, 2020.

26. Attached hereto as Exhibit 24 is a true and correct copy of excerpts of a letter from Eagle Pharmaceuticals to Office of Generic Drugs (HFD-600), FDA, enclosing [REDACTED] of ANDA No. 211538, dated September 11, 2019.

27. Attached hereto as Exhibit 25 is a true and correct copy of excerpts of the Executed Batch Record for [REDACTED] of ANDA No. 211538 [REDACTED].

28. Attached hereto as Exhibit 26 is a true and correct copy of excerpts of the Executed Batch Record for [REDACTED] of ANDA No. 211538 [REDACTED]

29. Attached hereto as Exhibit 27 is a true and correct copy of excerpts of the Executed Batch Record for [REDACTED] of ANDA No. 211538 [REDACTED]

30. Attached as Exhibit 28 are true and correct copies of excerpts of:

- a. Stability Data for Batch [REDACTED], dated February 6, 2020;
- b. Stability Data for Batch [REDACTED], dated February 6, 2020;
- c. Stability Data for Batch [REDACTED], dated February 6, 2020;
- d. Stability Data for Batch [REDACTED], dated February 6, 2020;
- e. Stability Data for Batch [REDACTED], dated March 19, 2020; and
- f. Stability Data for Batch [REDACTED], dated March 19, 2020.

31. Attached hereto as Exhibit 29 is a true and correct copy of excerpts of the Proposed Commercial Batch Record for Vasopressin Injection, USP, [REDACTED] of ANDA No. 211538 [REDACTED].

32. Attached hereto as Exhibit 30 is a true and correct copy of excerpts of Module 3.2.P.3.4 Control of Critical Steps and Intermediates, [REDACTED] [REDACTED] of ANDA No. 211538 [REDACTED].

I declare under penalty of perjury that the foregoing is true and correct.
Executed on: April 17, 2020.

/s/ Ashley Cade
Ashley Cade